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FDA: The Extremists Have It All Wrong

In the months since the November election, a consortium of far-right think tanks, lobbyists and public relations gurus have concocted a new mythology: the Food and Drug Administration, responsible for the safety of countless products used or consumed by Americans daily, is in fact an engine of death and unemployment. The message of their well-funded, multi-media advertising campaign is corrosive and blunt: "If a murderer kills you, it's homicide. If the FDA kills you, it's just being cautious."

The new mythology is being "stoked" by pseudo-facts and half-baked conjecture. And although rational observers can make reasonable criticisms of the FDA, the complete laundry list of complaints by these extremists reads like Grimm's Fairy Tales as rewritten by Stephen King.

Myth 1: The FDA drags its heels at the expense of dying Americans when entrepreneurs bring them experimental new drugs.

Fact: Patients can begin using an unapproved drug or device as soon as the manufacturer makes an investigational new drug (or device) application to the FDA. All the company typically has to do is present information that the drug or device is not inherently dangerous. The FDA and the maker of the product work together to assess the results. When the clinical evidence is solid, commercial distribution is usually approved.

For example, Eli Lilly and Co. received approval earlier this month for an anti-cancer drug under a new, accelerated decision process fashioned specifically for lifesaving products.

Myth 2: The FDA's bureaucracy-driven approval system kills jobs and softens America's competitive edge.

Fact: For small companies, the FDA certification of effectiveness is a guarantor of sales success at home and abroad. It provides small, undercapitalized firms that have tied their future to a single product with a Good Housekeeping seal of approval. Ask small manufacturers if their FDA approval helped them in overseas markets. Device sales alone have created a \$4.7 billion U.S. trade surplus.

Myth 3: The FDA approval process has kept scores of effective, lifesaving products off the market.

Fact: The agency process has kept many unsafe, ineffective and potentially dangerous products from U.S. consumers. In the case of the anti-cancer agent Interleukin 2, FDA trial requirements exposed significant safety problems that even the company eventually agreed were legitimate and reasonable.

In the case of the Sensor Pad, a device for detecting breast cancer tumors, FDA's critics suggested that the U.S. agency had been unreasonably tough while Canadian counterparts had let the device on the market there.

As it turns out, neither statement was correct. In yet another example, FDA's much-criticized approval process kept a new Alzheimer's drug off the market until investigators could figure out treatment methods that would not fatally damage patients' livers.

Myth 4: Industry and independent health experts overwhelmingly believe that a radical overhaul of FDA is warranted.

Fact: While few in the industry will argue FDA's perfection, most accept the fact that independent, unbiased and rigorous assessment of new products by the agency creates a gold standard necessary for global competitiveness.

Lisa Raines, vice president of government affairs for Genzyme Corp., says her company "is not interested in tearing FDA down" but wants to "take a good agency and make it better." Alan Magazine, president of the Health Industry Manufacturers Association, wants process reform, but adds, "I don't think that dismantling the FDA is in the best interests of citizens or the industry."

The American Heart Association, writing to the New York Times last month to protect the use of its name in an anti-FDA advertisement, stated "while we do not always agree with the FDA on particular issues, we believe it is committed to promoting and protecting the public's health."

Myth 5: The FDA's time-consuming, ever-

slowing, rope-a-dope approval system is creating huge backlogs and a stymied industry.

Fact: In some cases, the FDA process has been slow. But the numbers have improved dramatically over the past several years. Despite spurious claims to the contrary, the agency's evaluation time for breakthrough drugs has been cut by 51 percent in the past year alone—from 23.4 months to 12.2 months. The approval time for drugs deemed potentially lifesaving averaged 10.4 months. By 1997, the FDA expects that the approval time for breakthrough drugs, or for drugs with lifesaving potential, could be down to six months.

There's no agency on earth that can't be improved, and the FDA is no exception. Some devices and non-critical applications ought to be dropped from the regulatory system entirely. Requirements for early phase trials could be significantly reformed and streamlined as has been done in Europe. Entrepreneurs could save time and money if more of the agency's approval process were moved out of the Washington-based bureaucracy and into private, third-party reviews.

These and other ideas mark a path for constructive FDA reform. Alternative, myth-shrouded proposals being offered by the extremists would tear the fabric of the world's safest and most effective health care system.

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